83900-S2

NDA 83-900/S-002

Smith Kline & French Laboratories
Attention: J.F. Cassin
1500 Spring Garden Street
P.O. Box 7929
Philadelphia, PA 19101

Gentlemen:

We acknowledge receipt on April 12, 1977, of your communication of April 12, 1977. This is regarded as a supplemental new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amphetamine Sulfate Tablets, 5 mg.

The supplemental application provides for revised container labels.

We have completed the review of this supplemental application and it is approved. Our letter of February 26, 1976, detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
PHI Do
Dup
HFD-614 HFD-616
JVVkarusaitis/JMyer/MJarski
r/d/ init. JMeyer/MSeife 5-9-77
f/t/wlb/5-9-77
approved.

ORIG

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-900

DATE APPROVAL LETTER ISSUED:

TO: Press Relations Staff (HFI-40)

FROM:
- [ ] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

APPROVED

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [ ] ANDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

TRADE NAME *(or other designated name)* AND ESTABLISHED OR NONPROPRIETARY NAME *(if any)* OF DRUG

amphetamine sulfate

DOSAGE FORM

tablet

HOW DISPENSED
- [ ] RX
- [ ] OTC

ACTIVE INGREDIENT(S) *(as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)*

amphetamine sulfate 5 mg.

NAME OF APPLICANT *(Include City and State)*

Smith Kline & French Laboratories
Philadelphia, PA 19101

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

amphetamine

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

labeling revision

FORM PREPARED BY

NAME: majarski

DATE:

FORM APPROVED BY

NAME: jlmeyer

DATE:

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

AF Number 83-900/S-002

Original
Amendment
Supplement xxxxxx
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)

Smith Kline & French Laboratories
Philadelphia, PA 19101

Date(s) of Submission(s)

4-12-77

Purpose of Amendment/Supplement

revised container labels - expiration dating added

Pharmacological Category	Name Of Drug
amphetamine	amphetamine sulfate

Dosage Form(s)	Potency	How Dispensed
tablet	5 mg.	Rx xxxxx OTC ☐

Environmental Impact Analysis Report

Samples

Related IND/NDA/MF(s)

Labeling

see medical officer's review of 5-4-77

Biologic Availability

Establishment Inspection

Components, Composition, Manufacturing and Controls

Remarks

approval majarski

/S/ 5/9/77

Conclusion

Reviewer:

Date:

REVIEW OF SUPPLEMENT

DATE COMPLETED: 5-4-77

ANDA #: 83-900/S-002

CO. NAME: Smith Kline & French
Philadelphia, PA 19101

APPROVAL DATE: 2-26-76

NAME OF DRUG: Benzedrine Tablets 5 mg., 10 mg.
(Amphetamine sulfate 5 mg)

DATE OF SUBMISSION: 4-12-77

TYPE OF SUBMISSION: Supplement - labeling revision
Immediate container label revised.

CLINICAL EVALUATION:

1. Review of Labeling:

   a) Container labels: Satisfactory
   5 mg., bottles of 100
   will use "expiration" date in May 1977

   b) Insert labeling: not submitted

CONCLUSIONS: Container labeling is satisfactory for the safe and effective use of this product.

RECOMMENDATIONS: Approve supplement S-002.

/S/
V.V. Karusaitis, M.D.

cc:dup
VVK/wlb/5-5-77

SK&F

ORIG

SMITH KLINE &FRENCH LABORATORIES

1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101 • 215-854-4000

cable SMITHKLINE PHILADELPHIAPA
telex 83-4487

NDA 83-900
'Benzedrine' Tablets

April 12, 1977

Division of Generic Drug Products
Office of Drug Monographs
Bureau of Drugs HFD #530
Attn: Document Control Room 16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 83-900 PT ... S/002
NDA SUPPL FOR Labeling Revision

FPL

Gentlemen:

In accordance with § 314.8 (a)(5)(ix), I am enclosing 12 final printed copies of immediate container labels for 'Benzedrine' (brand of amphetamine sulfate) Tablets, 5 mg. (100's - Code AG) revised to add the word "Expires". No expiration date has been used previously for the 5 mg. strength of this product. This label will be placed in use in May.

Code AG also differs from prior labeling in that the NDC number has been changed from alpha-numeric to all numeric to facilitate adaptation into computerized drug programs.

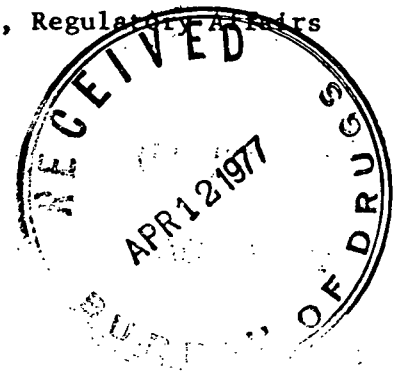
Similar label changes were submitted for the 10 mg. strength product October 15, 1975.

Stability data was incorporated in the Facilities and Controls Section 8, pages 11 and 12, of our original submission dated August 6, 1971 and later updated in our communication dated October 15, 1975 to substantiate a 5 year expiration date for both strengths of this product.

Sincerely,

J. F. Cassin

J. F. Cassin
Manager, Regulatory Affairs



att.
jm

Labeling: ORIG

NDA No: 83-900 Rc'd. 4-12-77

Reviewed by: [signature] 5/9/77

NDA 83-900

'BENZEDRINE' TABLETS

5 mg. - 100's

APPROVED MAY 11 1977 [signature]

APPROVED MAY 11 1977 [signature]

APPROVED MAY 11 1977 [signature]

100 tablets
NDC 0007-3191-20

5 mg.

100 tablets
NDC 0007-3191-20

5 mg.

100 tablets
NDC 0007-3191-20

5 mg.

CII

CAUTION – Federal law prohibits dispensing without prescription.

Benzedrine

brand of

amphetamine sulfate

Tablets

Smith Kline & French Laboratories
Div. of SmithKline Corp., Phila., Pa. 19101

TRADE MARK

STORE AT CONTROLLED ROOM TEMPERATURE

Each tablet contains amphetamine sulfate, 5 mg.

Usual Dosage: 5 to 10 mg., 3 times daily. See accompanying folder for complete prescribing information.

Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

EXPIRES

AG. LOT